

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION <hr/> THIS DOCUMENT RELATES TO: WAVE 4 ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO
EXCLUDE THE TESTIMONY OF MICHAEL KARRAM, M.D. REGARDING THE
SAFETY AND EFFICACY OF THE TVT-O PRODUCT**

Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' Wave 1 Motion to Exclude the Proposed Testimony of Michael Karram, M.D. Regarding the Safety and Efficacy of the TVT-O Product, Dkt. 2091 (motion), 2092 (memorandum in support), which Plaintiffs adopted and incorporated by reference in their Notice of Adoption, Dkt. 3611, with respect to all Wave 4 cases identified in Exhibit A to Plaintiffs' Notice.

Dr. Karram issued his Wave 4 general report on June 3, 2016. Plaintiffs have adopted their Motion to Exclude from Wave 1, which targeted Dr. Karram's **Wave 1** general expert report. Dr. Karram's Wave 1 report, as further described below, significantly varies from his Wave 4 report. Because Plaintiffs have not challenged Dr. Karram's Wave 4 testimony or report, their motion is irrelevant and should be denied.

ARGUMENT

Dr. Karram is an urogynecologist nationally and internationally known in the field of gynecologic surgery and advanced pelvic surgery, with a subspecialty in the field of Female Pelvic Medicine and Reproductive surgery. Karram General TVT/TVT-O Expert Report (June 3, 2016) at 1-2, attached hereto as Exhibit A (“6/3/16 TVT/TVT-O Report”). He is board-certified in obstetrics and gynecology since 1986 and female pelvic medicine and reconstructive surgery since 2014. *Id.* Dr. Karram has been in private practice since 1984, currently serving as the Director of Urogynecology at Seven Hills Women’s Health Centers in Cincinnati, Ohio (since 1998), Director of Fellowship Minimally Invasive Gynecologic Surgery at Christ Hospital in Cincinnati (sic) (since 2013), and the Medical Director of Pelvic Floor Center at Mercy West Hospital in Cincinnati (since 2015). *Id.* He is a member of the American Urogynecologic Society (AUGS), International Urogynecologic Association (IUGA), and the American Association of Gynecologic Laparoscopists (AAGL). *Id.* at 3. He has worked as a consultant, proctor, preceptor, and trainer for pharmaceutical companies, including for Ethicon for TVT and TVT-O. *Id.* at 2, 20-21. Dr. Karram is an expert in treating both stress urinary incontinence and pelvic organ prolapse, with extensive experience using both native tissue and augmented repairs. *Id.* at 1. He began using TVT in 1998 and has performed over 2,000 synthetic sling procedures. *Id.* at 4.

Dr. Karram is without question a bona fide expert in the fields of pelvic medicine generally and in the surgical treatment of pelvic organ prolapse and stress urinary incontinence specifically. In these cases, Dr. Karram intends to offer opinions generally addressing the utility and safety of various mesh devices, including TVT and TVT-O. These opinions are set forth in his 6/3/16 TVT/TVT-O Report, the report submitted in Wave 4 cases.

Plaintiffs' Motion, however, is not aimed at Dr. Karram's 6/3/16 TVT/TVT-O Report. Instead, Plaintiffs incorporated by reference a challenge to Dr. Karram's General TVT Report which was submitted in Wave 1 cases, attached as Exhibit B to Plaintiffs' Motion, Dkt. 2091-3 ("Wave 1 Report"). This Wave 1 Report was initially challenged by Plaintiffs in April of 2016, more than a month before Dr. Karram even finished his 6/3/16 TVT/TVT-O Report, and the two reports have many differences. For example, in their motion, Plaintiffs argue that Dr. Karram "failed to address the science regarding the TVT-O device." Plaintiffs' Memorandum, Dkt. 2092 at 6. In so arguing, Plaintiffs emphasize that the terms "TVT-O" and "TVT-Obturator" "do[] not appear in his entire report." *Id.* at 7. However, the term "TVT-O" appears over 40 times in the 6/3/16 TVT/TVT-O Report. Also included in the 6/3/16 TVT/TVT-O Report are photos specifically related to the TVT-O placement procedures as well as direct citations to TVT-O-specific studies and literature. *E.g., id.* at 12-13, 21. Plaintiffs simply cannot say that the 6/3/16 TVT/TVT-O Report fails to address the TVT-O device or the science of it.

Plaintiffs' arguments made with respect to Dr. Karram's Wave 1 Report are irrelevant and inapplicable to his 6/3/16 TVT/TVT-O Report. Because Plaintiffs failed to address the expert reports offered by Ethicon in Wave 4, Ethicon respectfully requests that the Court deny Plaintiffs' motion in full. Should the Court choose not to deny the Plaintiffs' Motion in full on these grounds, or otherwise allow Plaintiffs to modify their motion so as to target Dr. Karram's Wave 4 testimony and opinions, Ethicon respectfully requests the opportunity to fully brief its response to Plaintiffs' Motion at that time.¹

¹ Alternatively, Ethicon incorporates by reference its opposition brief arguments regarding Dr. Karram's qualification to opine regarding the safety and efficacy of mesh products as set forth in its Responses to Plaintiffs' Motions to Exclude the Testimony of Michael Karram, M.D. in Wave 1, Dkt. 2133, Wave 2, Dkt. 2524, and Wave 3, Dkt. 2951.

Respectfully submitted,

ETHICON, INC., ETHICON LLC, AND
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CERTIFICATE OF SERVICE

I hereby certify that on this day, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones

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